

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 26

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte PAUL YAO-CHEUNG WANG

Appeal No. 93-3228
Application 07/796,023¹

ON BRIEF

Before WILLIAM F. SMITH, ***Administrative Patent Judge***, and
McKELVEY, ***Senior Administrative Patent Judge***, and WALTZ,
Administrative Patent Judge.

WALTZ, ***Administrative Patent Judge***.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the
examiner's final rejection of claims 7 through 14, 21 through

¹ Application for patent filed November 22, 1991. According to appellant, the application is a division of Application 07/063,968, filed June 19, 1987, now Patent No. 5,110,595, granted May 5, 1992, which is a continuation-in-part of Application 07/016,845, filed February 20, 1987, now abandoned.

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25 and 28 through 31, which are all of the claims remaining in this application.

According to appellant, the invention is directed to a bioerodible preparation implant with sustained action achieved by compressing an admixture of a solid active agent with solid lipid powder (brief, page 2).

Claim 7 is illustrative of the subject matter on appeal and is reproduced below:

7. A bioerodible preparation implant with sustained action which consists essentially of a compressed admixture of an effective amount of solid bioactive polypeptide with lipid powder, with the said lipid powder being selected from the group consisting of glycerides, waxes, long-chain fatty acids or derivatives, phospholipids, sphingolipids, cerebrosides, terpenes, non-hormonal steroids or a combination thereof.

The examiner has relied upon the following references:

Kent	4,452,775	Jun.
5, 1984		
Kidron	4,579,730	Apr. 1,
1986		
Jang	4,882,167	Nov.
21, 1989		
Nakagame et al. (EP '949)	0 143 949	Jun. 12,
1985		
(Published European Patent Application)		

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Claims 7-11, 14, 21, 22, 25 and 28-31 stand rejected under 35 U.S.C. § 102(b) as anticipated by Kent. Claim 7 stands rejected under 35 U.S.C. § 102(b) as anticipated by EP '949. Claims 7 and 8 stand rejected under 35 U.S.C. § 102(b) as anticipated by Kidron. Claims 7-13, 21-24 and 28-31 stand rejected under 35 U.S.C. § 103 as unpatentable over Jang in view of Kent. We vacate all of the stated rejections and, pursuant to the provisions of 37 CFR § 1.196(b), enter a new ground of rejection of claims 7-14, 21-25 and 28-31 under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which applicant regards as his invention. We also include a statement under 37 CFR § 1.196(c).

OPINION

A. The New Ground of Rejection Under 37 CFR § 1.196(b)

The limitations of appealed claim 7 are that the implant is bioerodible with sustained action and ?consists essentially of? a compressed admixture of an effective amount of a solid

bioactive polypeptide with lipid powder. The lipid powder may be, *inter alia*, solid lipids, cholic acid, or preferably cholesterol (specification, page 8, lines 2-19). The bioactive polypeptide may be insulin or somatotropin² (*id.*, page 1, lines 10-14, and page 3, lines 2-3).

A major point of contention between appellant and the examiner is the meaning or scope of the claimed term "consisting essentially of" (brief, pages 3-5, and the answer, pages 3 and 9-11). The meaning of the phrase "consisting essentially of" is well settled. The CCPA in *In re Janakirama-Rao*³ defines "consisting essentially of" as follows:

The word "essentially" opens the claims to the inclusion of ingredients which would *not* materially affect the *basic* and *novel* characteristics of appellant's compositions as defined in the balance of the claim... (emphasis in original).

² The examiner has used the word "somatotropin" and the term "growth hormone" interchangeably (answer, page 3, line 3). Appellant has not contested this usage.

³ 317 F.2d 951, 954, 137 USPQ 893, 896 (CCPA 1963). See also *In re DeLajarte*, 337 F.2d 870, 873-74, 143 USPQ 256, 258 (CCPA 1964), discussed on pages 3-4 of the brief, and *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948).

In construing the phrase "consisting essentially of" in appellant's claims, it is necessary and proper to determine whether the specification reasonably supports a construction which would include the materials of the cited prior art. See *In re Herz*, 537 F.2d 549, 551, 190 USPQ 461, 463 (CCPA 1976). Appellant's specification, under the heading "Summary of the Invention", states that the invention is that "lipid powder is simply admixed with a suitable amount of bioactive macromolecule, and compressed into a disc or rod without any other components." (specification, sentence bridging pages 7 and 8, emphasis added). From the remainder of appellant's specification, including the examples, there is no disclosure or teaching that any components can be employed in the implant other than the claimed solid bioactive polypeptide and lipid powder.⁴

The legal standard for definiteness under paragraph two of 35 U.S.C. § 112 is whether a claim reasonably apprises those of skill in the art of its scope. See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 927

⁴ See the specification, page 8, lines 25-28, page 9, lines 13-25, and Examples 1-5 on pages 11-21.

F.2d 1200, 1217, 18 USPQ2d 1016, 1030 (Fed. Cir. 1991). An otherwise definite claim may take on an unreasonable degree of uncertainty upon a reading of the specification disclosure. See *In re Moore*, 439 F.2d 1232, 1235 n.2, 169 USPQ 236, 238 n.2 (CCPA 1971). Where, as here, there is an ambiguity between the well settled meaning of "consisting essentially of" and the construction of the claimed subject matter as explicitly described in the specification, it is apparent that one of ordinary skill in the art would not be reasonably apprised of the scope of the claims. If appellant discloses in the specification that no components are present in the implant other than the bioactive macromolecule and the lipid powder, but the well accepted meaning of the claim includes other components as long as the basic and novel characteristics of the claimed composition are not materially affected, appellant is not particularly pointing out and distinctly claiming the subject matter he regards as his invention as required by the second paragraph of 35 U.S.C. § 112.

For the foregoing reasons, we enter a new ground of

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rejection pursuant to 37 CFR § 1.196(b) of claims 7-14, 21-25 and 28-31 under 35 U.S.C. § 112, second paragraph.

B. Statement Under 37 CFR § 1.196(c)

All of the prior art applied by the examiner in rejecting the claims on appeal contains components other than a bioactive macromolecule and a lipid powder (see the analysis of the references on pages 3-6 of the answer). Because the subject matter defined by the claims is not clear, it is not possible to assess whether this subject matter would have been anticipated under § 102 or unpatentable under § 103. See *In re Steele*, 305 F.2d 859, 862-63, 134 USPQ 292, 295-96 (CCPA 1962). Accordingly, we have vacated all four prior art rejections.

The claims on appeal, if amended to read "consisting of" instead of the presently claimed phrase "consisting essentially of", would avoid the foregoing new ground of rejection under 35 U.S.C. § 112, second paragraph. The term "consisting of" has the accepted meaning of closing the claim to the inclusion of materials other than those recited except

for impurities ordinarily associated therewith.⁵ The insertion of "consisting of" into the claims on appeal would obviate the new ground of rejection entered above since the scope of the amended claims would be consistent with the disclosure and teachings of the specification. The examiner should re-evaluate the patentability of the subject matter in any amended claims in view of the above remarks and the prior art.

The examiner and appellant should reconcile the scope of the language of claims 7 and 8, if amended pursuant to our statement under 37 CFR § 1.196(c), with the language of dependent claims 11 and 29-31. Specifically, the kit of claims 11 and 31 and the bioerodible preparation of claims 29 and 30 all recite the term "comprises" but these claims ultimately depend on claims 7 and 8. The meaning or scope of the term "comprises" is well settled. The term "comprises" leaves the claim open for the inclusion of unspecified

⁵ See *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948), and cases cited in footnote 3 *supra*.

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ingredients even in major amounts.⁶ Therefore, upon amendment, the examiner and appellant should reconcile the scope of the claims.

This decision contains a new ground of rejection pursuant to 37 CFR § 1.196(b)(amended effective Dec. 1, 1997, by final rule notice, 62 Fed. Reg. 53,131, 53,197 (Oct. 10, 1997), 1203 Off. Gaz. Pat. & Trademark Office 63,122 (Oct. 21, 1997)). 37 CFR

§ 1.196(b) provides that, "A new ground of rejection shall not be considered final for purposes of judicial review."

37 CFR § 1.196(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of proceedings (§ 1.197(c)) as to the rejected claims:

(1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application

⁶ See *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948). See also *In re Baxter*, 656 F.2d 679, 686-87, 210 USPQ 795, 802-03 (CCPA 1981).

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will be remanded to the examiner. . . .

(2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record. . . .

37 CFR § 1.196(c) provides:

Should the decision of the Board of Patent Appeals and Interferences include an explicit statement that a claim may be allowed in amended form, appellant shall have the right to amend in conformity with such statement which shall be binding upon the examiner in the absence of new references or grounds of rejection.

A statement pursuant to 37 CFR § 1.196(c) has been made in this decision. A time period in which appellant may file an amendment for the purpose stated in § 1.196(c) is hereby set to expire TWO MONTHS FROM THE DATE OF THIS DECISION.

No time period for taking subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

VACATED - 37 CFR § 1.196(b) and (c)

WILLIAM F. SMITH)
Administrative Patent Judge)
)

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FRED E. McKELVEY, Senior
Administrative Patent Judge

THOMAS A. WALTZ
Administrative Patent Judge

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